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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,599	02/20/2002	Cornelia Anna Mundt	GJE-87	9658
23557	7590	03/24/2004	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION 2421 N.W. 41ST STREET SUITE A-1 GAINESVILLE, FL 326066669			QIAN, CELINE X	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8-14-
Office Action Summary

Application No.

10/081,599

Applicant(s)

MUNDT ET AL.

Examiner

Celine X Qian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 5-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/10/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I in the response filed on 2/23/04 is acknowledged. The traversal is on the ground(s) that a search of Group I and Group IV can be made without undue burden. This is not found persuasive because the inventions of Groups I and IV are patentably distinct for reasons set forth of the record mailed on 1/29/04. Briefly, invention I is directed to an artificial chromosome comprising a region between C δ and C γ 3 of human IgH, whereas invention IV is directed to a polynucleotide comprising a functional enhancer or other modifier between C δ and C γ 3 and a heterologous gene, which are structurally and functionally different nucleic acid molecules. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the artificial chromosome of Group I can be used to expressing IgH in a transgenic mouse, whereas the polynucleotide of Group IV can be any plasmid or viral vectors that express a heterologous protein in cell culture. A search of Group I is not co-extensive with the search of the Group IV. Therefore, the search is burdensome.

Newly submitted claim 14 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 14 is drawn to an artificial chromosome comprising an expression modifier and a heterologous gene, which belongs to the invention of Group IV. It is not related to the invention of Group I because it is structurally and functionally distinct from the artificial chromosome of Group I in which it comprises a

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heterologous gene under the control of an expression modifier. Therefore, the inventions are patentably distinct. As discussed above, a search of the invention of Group I is not co-extensive with a search of the invention of Group IV.

Since applicant is receiving an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 14 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Since Applicant did not distinctly and specifically point out the supposed error of the restriction requirement, for same reason given in the previous office action and above, the restriction requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 5-14 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1-4 and 15 are currently under examination.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is set forth by 35 U.S.C. 112, first paragraph which states that the: “*specification* shall contain a written description of the invention. . .[emphasis added].” The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that “as of the filing date sought, [the inventor] was in possession of the invention.” See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in “possession” of the invention claimed by describing the invention with all of its claimed limitations “by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

In analyzing whether the written description requirement is met, it is first determined whether a representative number of species have been described by their complete structure. Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. The claims recite an artificial chromosome including “a region between C δ and C γ 3 of human IgH locus, or a functional variant part thereof.” This region potentially encompasses a large genus of nucleic acids of different size and/or function because the region between C δ and C γ 3 of human IgH locus is of 52kb and comprises many cis-elements. The specification only discloses a specific 1.3kb region between the C δ and C γ 3 of human IgH locus has enhancer function in early lymphoid

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development. The specification does not teach any other function(s) for the rest of the region. Furthermore, the specification fails to describe what is the structural characteristic the claimed region(s) must share for their function. As such, the specification fails describe a representative number of species by neither their complete structure nor other identifying characteristics. Therefore, the written description requirement is not met.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1-4 and 15, the term “functional part thereof” renders the claims indefinite because it is unclear what function Applicants are referring to. It is unclear what is the function for a region between C δ and C γ 3 of IgH locus.

Regarding claim 3, the term “transcription-binding factor” renders the claim indefinite because it is unclear how the chromosome(which is made up by DNA) could comprise a protein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Turgeon et al (JMB, January 21, 2000, Vol.295 No.3, page 489-504).

The claims are drawn to an artificial chromosome including a region which is between C δ and C γ 3 of the human IgH locus, or a functional part thereof (1). The claims are further drawn to said artificial chromosome wherein it is of bacterial, yeast, eukaryotic or mammalian origin (2). Claim 3 is drawn to said chromosome wherein it includes a transcription binding element.

Turgeon et al. disclose an artificial chromosome of bacterial origin (PAC 21598) that comprises a number of putative cis-acting elements including C/EBP, AP-1, Oct-1 and NF- κ B (see page 491, 1st col., 3rd paragraph, lines 5-8, and page 493, 1st col., 1st paragraph, and Figure 3). Although cis-element C/EBP and Oct-1 are not from the region between C δ and C γ 3 region of human IgH, their sequence is nevertheless the same. The specification discloses these two elements are also found in the region between C δ and C γ 3. Thus, the artificial chromosome disclosed by Turgeon et al. is structurally same as the claimed invention. Therefore, Turgeon et al. disclose the instantly claimed inventions.

Claims 1, 2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Larionov et al (PNAS, 1996, Vol. 93, pages 13925-13930).

Claims 4 is drawn to an artificial chromosome that comprises a region between C δ and C γ 3 region of human IgH, wherein it includes a 1, 2 or 3 repeat sequence.

Larionov et al. disclose YACs that comprises Alu repeat sequences (see abstract and Figure 1b, and page 13926 2nd col., 6th paragraph through 13927, 1st col). Although the Alu repeats are not from the region between C δ and C γ 3 region of human IgH, their sequence is

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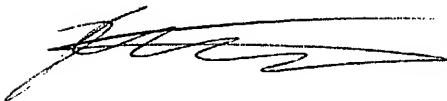
nevertheless the same. The specification discloses Alu repeats are also found in the region between C δ and C γ 3. Thus, the artificial chromosome disclosed by Larionov et al. is structurally same as the claimed invention. Therefore, Larionov et al. disclose the instantly claimed inventions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.

A handwritten signature in black ink, appearing to be 'Celine Qian', with a stylized, flowing script.